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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,064	09/25/2006	**Janine T. Bryan**	21571P	5405

210 7590 04/07/2009

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EXAMINER	
GEBREYESUS, KAGNEW H	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
04/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,064	BRYAN ET AL.	
	Examiner	Art Unit	
	KAGNEW H. GEBREYESUS	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7 are drawn to A nucleic acid molecule comprising a sequence of nucleotides that encodes an HPV52 L1 protein as set forth in SEQ ID NO:2, the nucleic acid sequence being codon-optimized for high-level expression in a yeast cell, vector and host cell comprising the nucleic acid

Group II, claim(s) claims 8-15, 17-23, 25 and 27 drawn to virus-like particles (VLPs) comprised of recombinant L1 protein of HPV52, wherein the recombinant L1 protein is produced in yeast.

Group III, claims 8-15, 17-23, 25 and 27 or drawn to virus-like particles (VLPs) comprised of recombinant L1 +L2 protein of HPV52, wherein the recombinant L1 + L2 proteins are produced in yeast.

The technical feature linking the invention first claimed is a codon optimized DNA construct that encodes an HPV 52 protein. However this technical feature is not a special technical feature because of the combined teaches of US 5,643,715 Lancaster et al Sharp et al (1991) and Hofmann et al (1995). US 5,643,715 Lancaster et al teach an isolated nucleic acid molecule comprising a sequence of nucleotides that encodes an HPV52 L1 protein. Furthermore they teach that cloning vectors comprising HPV 52 DNA or fragments can be expressed in bacterial or eukaryotic host cells. (See column 6 last paragraph).

Sharp et al (1991) teach different degrees of codon usage in *Saccharomyces cerevisiae* from which an optimal codon for expression in *Saccharomyces cerevisiae* can be selected (see table 2 on page 673).

Hofmann et al (1995) teach that the major (L1) and minor (L2) proteins of HPV proteins are promising candidate targets for producing vaccines (immunoprophylaxis). They further teach that the *Saccharomyces cerevisiae* yeast expression system exhibits many advantages for the development of vaccine. Hofmann et al do not teach expressing HPV52 from codon optimized the HPV52 DNA.

Thus it would have been obvious for one of ordinary skill in the art to use *Saccharomyces cerevisiae* to express the HPV 52 L1 and L1+L2 genes in *Saccharomyces cerevisiae* for the many advantages discussed in Hofmann et al. They teach that yeast have the potential to produce large quantities of proteins in their native conformation; it has the apparatus for some post translational modifications similar to those of mammalian cells and that yeast derived products for human use have been

accepted from the regulatory standpoint. They further teach production of VLPs from HPV6a L1 and L1+L2 in yeast. (see page 507 1st paragraph). Thus following this model an ordinary skill in the art would be motivated to produce VLPs from HPV52 L1 and L1+L2 vaccine in *Saccharomyces cerevisiae*. This is because HPV 52 is one among many human papillomaviruses (HPV) serotypes that known to be associated with disease (see for example Zhao et al (US 6,436402) column 3 lines 29-40). Therefore the technical feature linking the invention of group I and II is not a special technical feature as it does not contribute over the prior art as required in PCT rule 13.2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kagnew H Gebreyesus/
Examiner, Art Unit 1656
4/1/2009

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657